Food and Drug Administration Center for Biologics Evaluation and Research

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting # 36

Holiday Inn, Gaithersburg, MD October 9-10, 2003

AGENDA

Thursday October 9, 2003

Session 1: Allogeneic Islet Transplantation

8:00 a.m. Opening and Introduction of Committee

Dr. Mahendra Rao, Acting Chair, BRMAC

8:10 Conflict of Interest Meeting Statement

Gail Dapolito, Executive Secretary, BRMAC

8:15 FDA Introduction

Dr. Philip Noguchi

Acting Director, Office of Cellular, Tissue and Gene Therapies (OCTGT)

Center for Biologics Evaluation and Research, FDA

Dr. Jesse Goodman

Director

Center for Biologics Evaluation and Research, FDA

Federal Oversight of Allogeneic Islet Transplantation

8:35 Overview of FDA Regulatory Issues

Dr. Darin Weber

Chief, Cell Therapy Branch, Division of Cellular and Gene Therapies (DCGT)

Center for Biologics Evaluation and Research, FDA

8:45 HRSA's Role in Pancreas and Islet Transplantation

Dr. Jim Burdick

Director, Division of Transplantation

Office of Special Programs

Health Resources and Services Administration

9:05 Moving from Investigational Islet Products to Licensed Islet Products

Expectations for Facilities & cGMPs

Dr. Nicholas Obiri

Microbiologist, Division of Compliance and Biologics Quality

Center for Biologics Evaluation and Research, FDA

9:25 Processing and Product Quality Issues, Assessing the Final Product

Dr. Keith Wonnacott

Microbiologist, Cell Therapy Branch, DCGT

Center for Biologics Evaluation and Research, FDA

9:45 Q&A

10:05 a.m. Break

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AGENDA (cont'd)

Thursday October 9, 2003

4:35 p.m.

Thursday October 9, 2003		
Session	on 1: Allogeneic Islet Transplantation (Cont'd)	
10:20 a.m.	FDA Introduction to Guest Presentations Dr. Darin Weber Chief, Cell Therapy Branch, DCGT Center for Biologics Evaluation and Research, FDA	
10:30	Islet Processing: Evolution and Current Standards Dr. Camillo Ricordi Professor of Surgery, Department of Surgery University of Miami	
10:55	Q&A	
11:10	Current Status of Islet Characterization and Quality Dr. Bernhard Hering Associate Professor of Surgery, Department of Surgery University of Minnesota	
11:35	Q&A	
11:50	Open Public Hearing	
12:20 p.m.	Lunch	
1:30	Committee Discussion of Questions	
3:00	Break	
3:15	Committee Discussion of Questions (cont'd)	
Session	Update of Research Programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins	
4:15	Introduction – Laboratory of Stem Cell Biology and Laboratory of Immunology and Virology, Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapies Dr. Raj Puri Acting Director, DCGT, OCTGT Center for Biologics Evaluation and Research	
4:20	Laboratory of Immunology and Virology Dr. Carolyn Wilson Senior Investigator, Laboratory of Immunology and Virology (LIV), DCGT	
4:30	Dr. Andrew Byrnes Senior Staff Fellow, LIV, DCGT	

Dr. Nancy Markovitz Senior Staff Fellow, LIV, DCGT

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AGENDA (cont'd)

Thursday October 9, 2003

Session 2: Update of Research Programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins

4:40 p.m. Laboratory of Stem Cell Biology

Dr. Steven Bauer

Acting Chief, Laboratory of Stem Cell Biology, DCGT Center for Biologics Evaluation and Research, FDA

4:45 Introduction – Laboratory of Biochemistry, Division of Therapeutic Proteins,

Office of Biotechnology Products

Dr. Amy Rosenberg

Director, Division of Therapeutic Proteins

Office of Biotechnology Products

Center for Drugs Evaluation and Research, FDA

4:50 Laboratory of Biochemistry

Dr. Emily Shacter

Chief, Laboratory of Biochemistry

4:55 Break

Closed Session

5:50 p.m. Adjourn

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AGENDA (cont'd)

Friday October 10, 2003

8:00 a.m.	Opening/Administrative Remarks Dr. Mahendra Rao, Acting Chair, BRMAC
8:10	FDA Introduction Dr. Cynthia Rask Director, Division of Clinical Evaluation and Pharmacology/Toxicology, OCTGT Center for Biologics Evaluation and Research, FDA
8:25	Current Status of Clinical Islet Transplantation Dr. James Shapiro Clinical Research Chair in Transplantation University of Alberta, Canada
8:50	Q&A
9:05	Allocation of Pancreata for Whole Organ and Islet Transplantation Dr. Jim Burdick Director, Division of Transplantation, HRSA
9:25	Q&A
9:40	Ethical Considerations in Allogeneic Islet Transplantation Dr. James Childress John Allen Hollingsworth Professor of Medicine University of Virginia
10:05	Q&A
10:20 10:45	Clinical Development of Islet Products Dr. Dwaine Rieves Medical Officer, Division of Clinical Evaluation and Pharmacology/Toxicology, OCTGT Center for Biologics Evaluation and Research, FDA Q&A
11:00	Open Public Hearing
	Open I uone Heming
11:30	Lunch
12:00 noon	Committee Discussion of Questions
2:00 p.m.	Adjourn